Changes to laboratory based HIV diagnosis and GP liaison experiences

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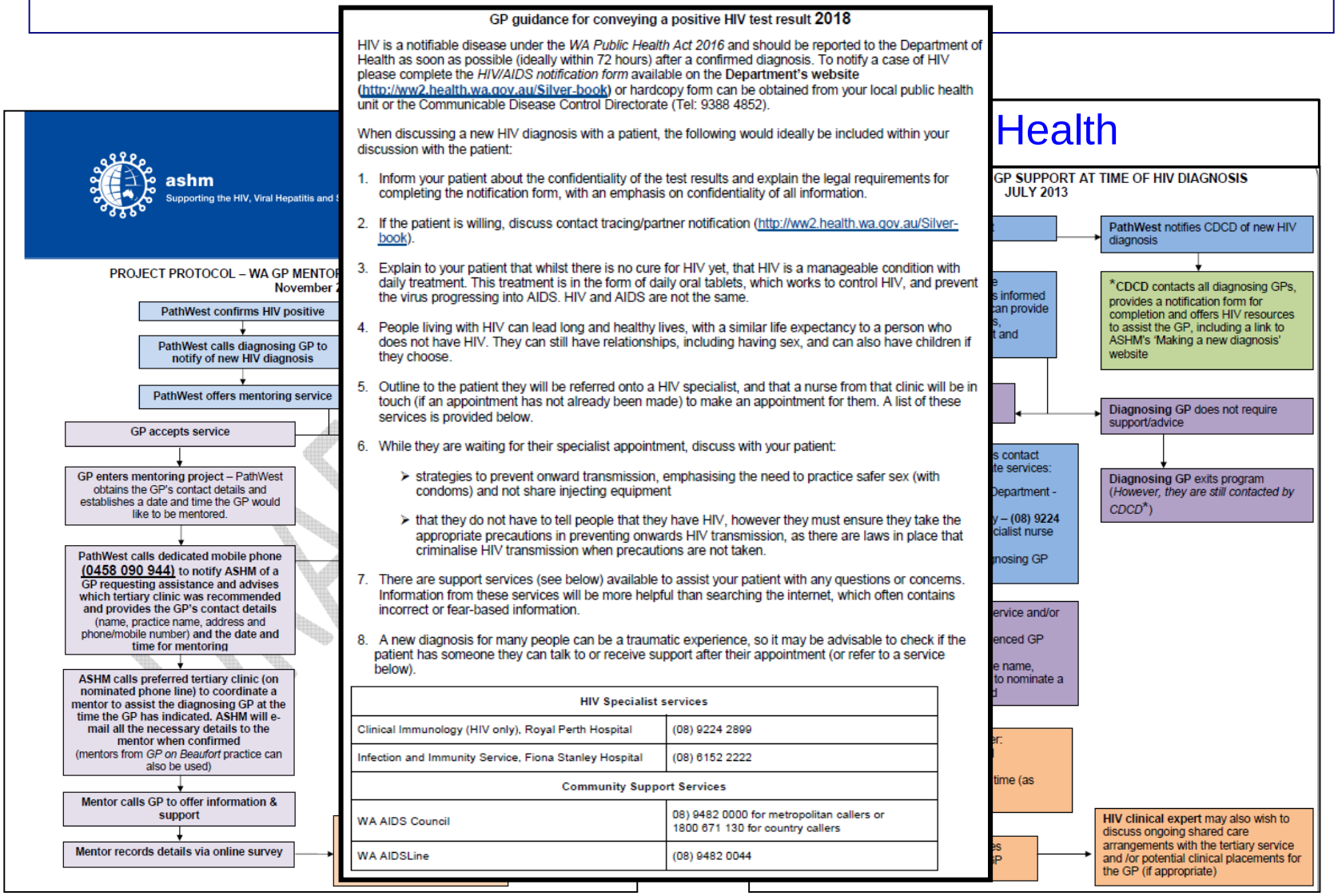
New HIV diagnoses

- WA New HIV Diagnosers (GP Mentoring) Project
  - commenced July 2009, coordinated by ASHM for WA Health
    - As part of WA HIV Model of Care 2010 in line with the national HIV/AIDS Strategy 2005
    - Also conducted in NSW

YEAR	Accepted	Declined	Acceptance (%)
2009	11	9	55
2010	12	18	40
2011	5	14	26

  - Modified 2011-2012
  - Transferred to Communicable Diseases Branch WA Health 2013
  - Linked to WA STI Mx Guidelines ('Silver Book') 2018

GP Time of Dx Mentoring Project



ashm
Supporting the HIV, Viral Hepatitis and

PROJECT PROTOCOL – WA GP MENTOR
November

PathWest confirms HIV positive

PathWest calls diagnosing GP to notify of new HIV diagnosis

PathWest offers mentoring service

GP accepts service

GP enters mentoring project – PathWest obtains the GP's contact details and establishes a date and time the GP would like to be mentored.

PathWest calls dedicated mobile phone **(0458 090 944)** to notify ASHM of a GP requesting assistance and advises which tertiary clinic was recommended and provides the GP's contact details (name, practice name, address and phone/mobile number) **and the date and time for mentoring**

ASHM calls preferred tertiary clinic (on nominated phone line) to coordinate a mentor to assist the diagnosing GP at the time the GP has indicated. ASHM will e-mail all the necessary details to the mentor when confirmed (mentors from *GP on Beaufort* practice can also be used)

Mentor calls GP to offer information & support

Mentor records details via online survey

GP guidance for conveying a positive HIV test result 2018

HIV is a notifiable disease under the *WA Public Health Act 2016* and should be reported to the Department of Health as soon as possible (ideally within 72 hours) after a confirmed diagnosis. To notify a case of HIV please complete the *HIV/AIDS notification form* available on the **Department's website** (http://ww2.health.wa.gov.au/Silver-book) or hardcopy form can be obtained from your local public health unit or the Communicable Disease Control Directorate (Tel: 9388 4852).

When discussing a new HIV diagnosis with a patient, the following would ideally be included within your discussion with the patient:

1. Inform your patient about the confidentiality of the test results and explain the legal requirements for completing the notification form, with an emphasis on confidentiality of all information.
2. If the patient is willing, discuss contact tracing/partner notification (http://ww2.health.wa.gov.au/Silver-book).
3. Explain to your patient that whilst there is no cure for HIV yet, that HIV is a manageable condition with daily treatment. This treatment is in the form of daily oral tablets, which works to control HIV, and prevent the virus progressing into AIDS. HIV and AIDS are not the same.
4. People living with HIV can lead long and healthy lives, with a similar life expectancy to a person who does not have HIV. They can still have relationships, including having sex, and can also have children if they choose.
5. Outline to the patient they will be referred onto a HIV specialist, and that a nurse from that clinic will be in touch (if an appointment has not already been made) to make an appointment for them. A list of these services is provided below.
6. While they are waiting for their specialist appointment, discuss with your patient:
   - strategies to prevent onward transmission, emphasising the need to practice safer sex (with condoms) and not share injecting equipment
   - that they do not have to tell people that they have HIV, however they must ensure they take the appropriate precautions in preventing onwards HIV transmission, as there are laws in place that criminalise HIV transmission when precautions are not taken.
7. There are support services (see below) available to assist your patient with any questions or concerns. Information from these services will be more helpful than searching the internet, which often contains incorrect or fear-based information.
8. A new diagnosis for many people can be a traumatic experience, so it may be advisable to check if the patient has someone they can talk to or receive support after their appointment (or refer to a service below).

HIV Specialist services	
Clinical Immunology (HIV only), Royal Perth Hospital	(08) 9224 2899
Infection and Immunity Service, Fiona Stanley Hospital	(08) 6152 2222
Community Support Services	
WA AIDS Council	08) 9482 0000 for metropolitan callers or 1800 671 130 for country callers
WA AIDSLine	(08) 9482 0044

Health

GP SUPPORT AT TIME OF HIV DIAGNOSIS
JULY 2013

PathWest notifies CDCD of new HIV diagnosis

*CDCD contacts all diagnosing GPs, provides a notification form for completion and offers HIV resources to assist the GP, including a link to ASHM's 'Making a new diagnosis' website

Diagnosing GP does not require support/advice

Diagnosing GP exits program (*However, they are still contacted by CDCD**)

HIV clinical expert may also wish to discuss ongoing shared care arrangements with the tertiary service and /or potential clinical placements for the GP (if appropriate)

Current Australian (PHLN) laboratory diagnosis

Definitive Criteria for Confirmed case in Children aged >18 months and Adults:

Repeatedly reactive results on screening assay

AND

Positive results on western blot assay or line probe immunoassay

OR

Positive p24 antigen assay, including neutralisation on two separate specimens

OR

HIV isolation

- Consequence for early HIV infection:
  - line probe immunoassay not available in Australia
  - two positive p24 Ag results rarely achieved and HIV isolation not performed
  - most work-up of a new HIV diagnosis (viral load, CD4 count, opportunistic infection screening) is often completed before the Western Blot has seroconverted to positive

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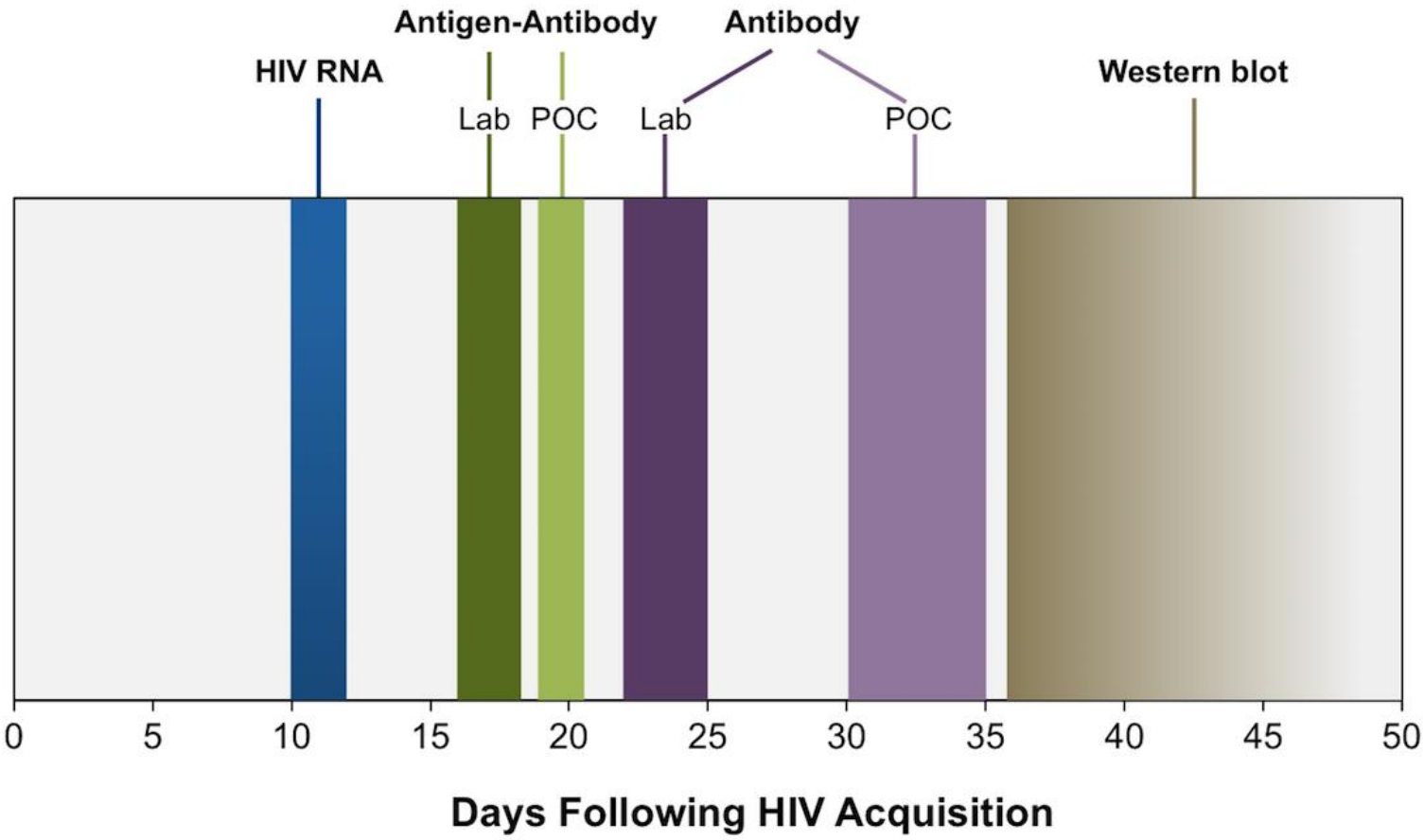
2013 NPAAC requirements for laboratory testing for HIV and HCV currently require Western Blot confirmation of HIV infection

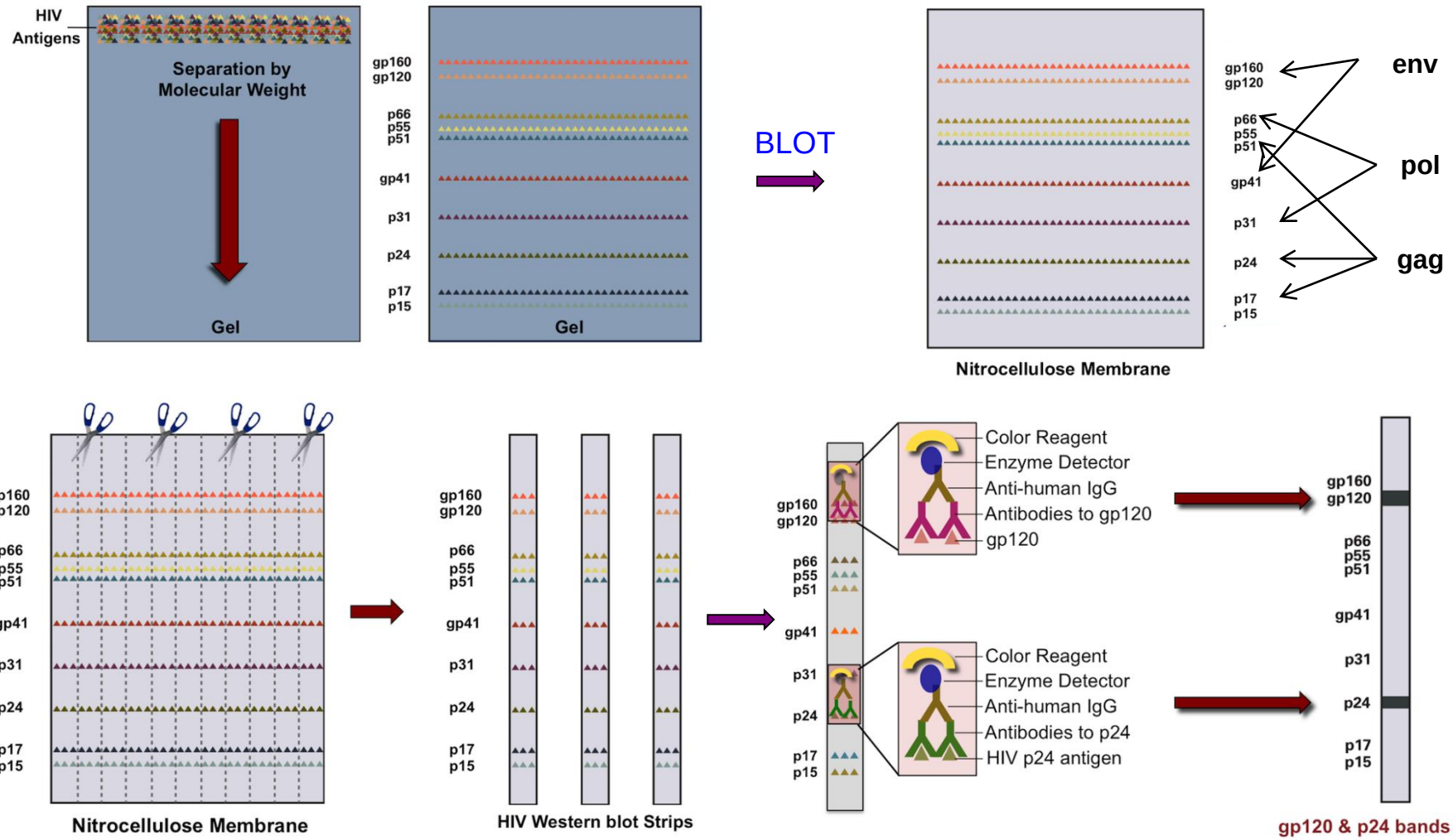
Public health response impact at the acute HIV stage

Acute HIV markers



https://www.hiv.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all.

Western Blot



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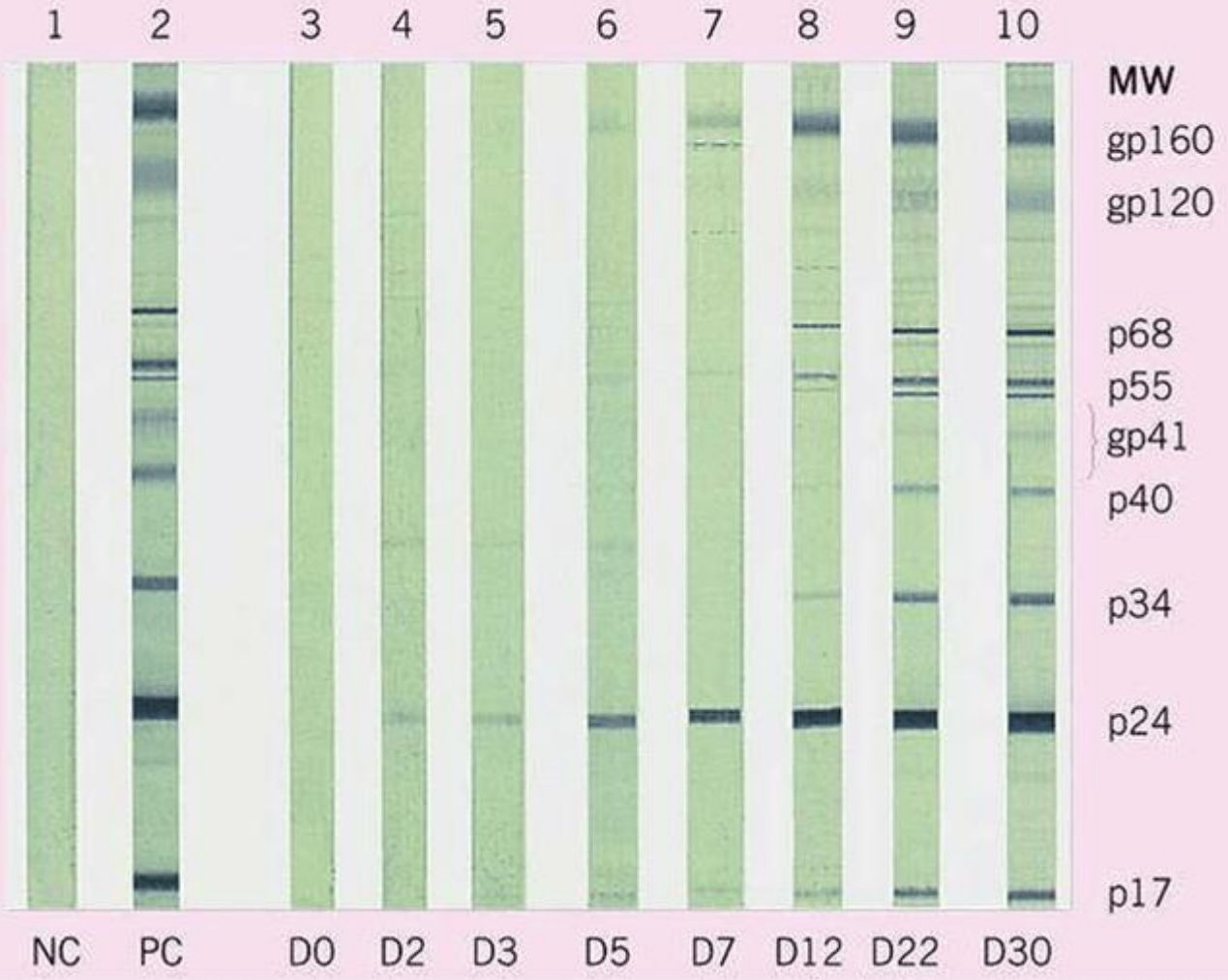
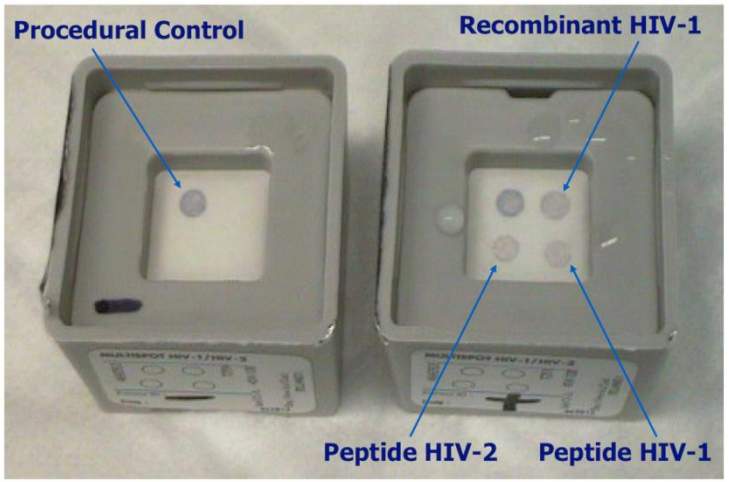
WESTERN BLOT REACTIVITY IN ONE HIV-1 SEROCONVERTER



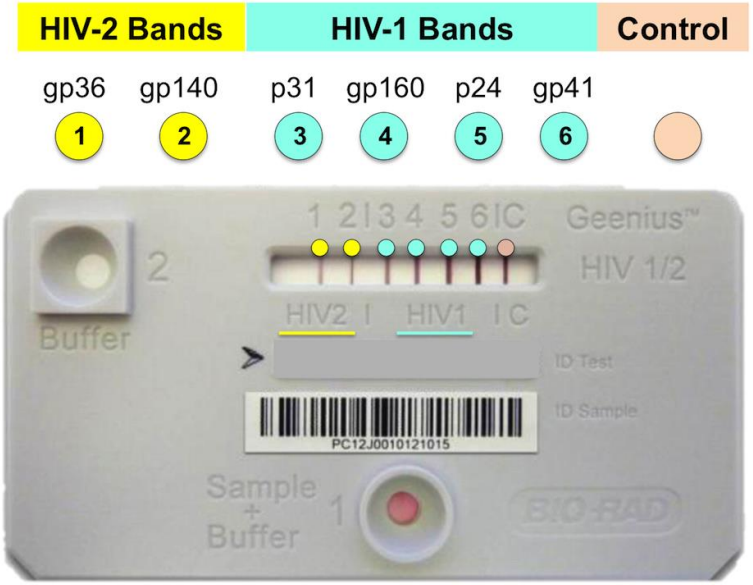
CDC use Ab Differentiation Tests for supplemental testing for HIV-1/2

- immunochromatographic tests

Multispot HIV-1/HIV-2

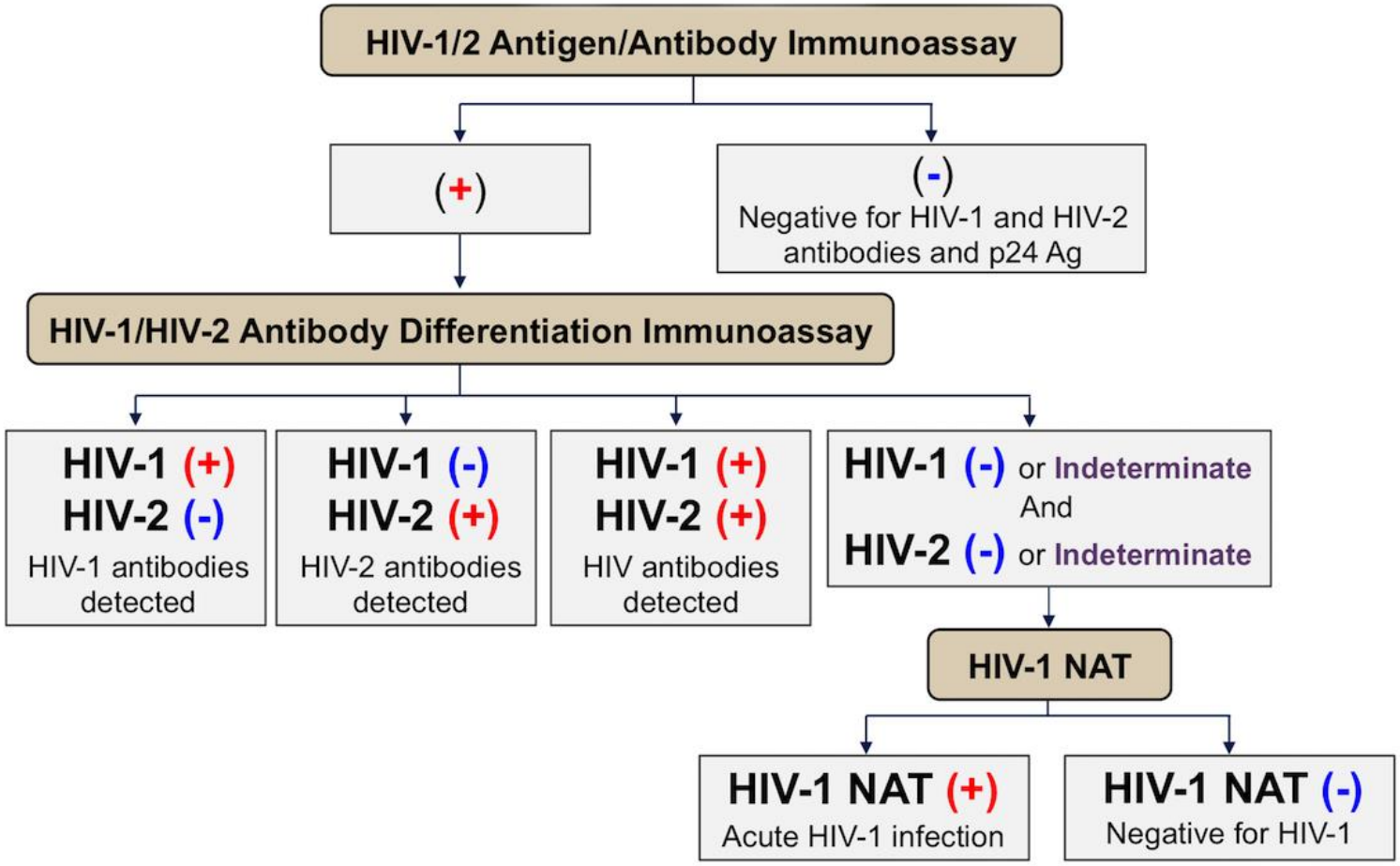


Geenius HIV 1/2 Assay

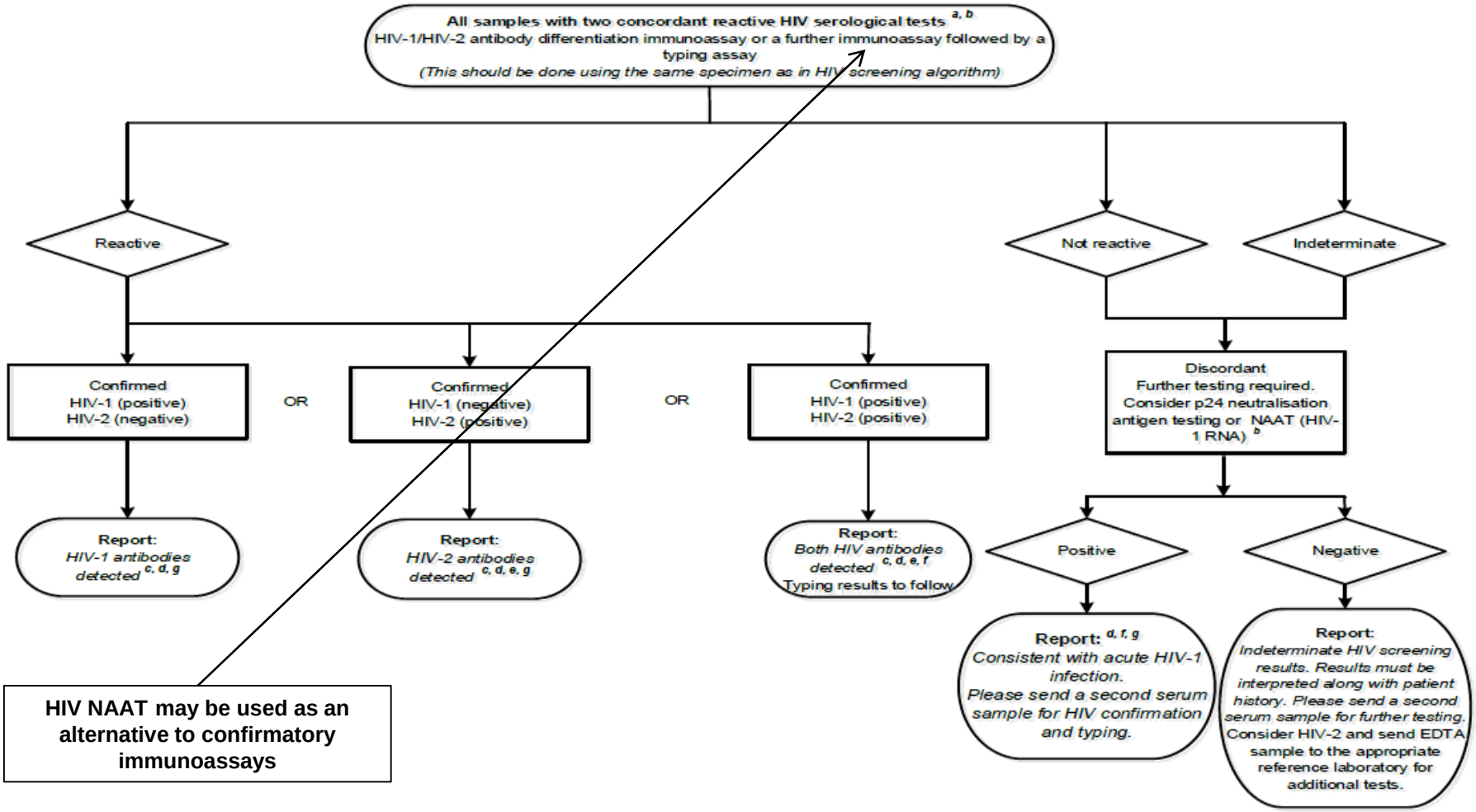


https://www.hiv.uw.edu/go/screening-diagnosis/diagnostic-testing/core-concept/all.

CDC and APHL HIV testing algorithm 2018

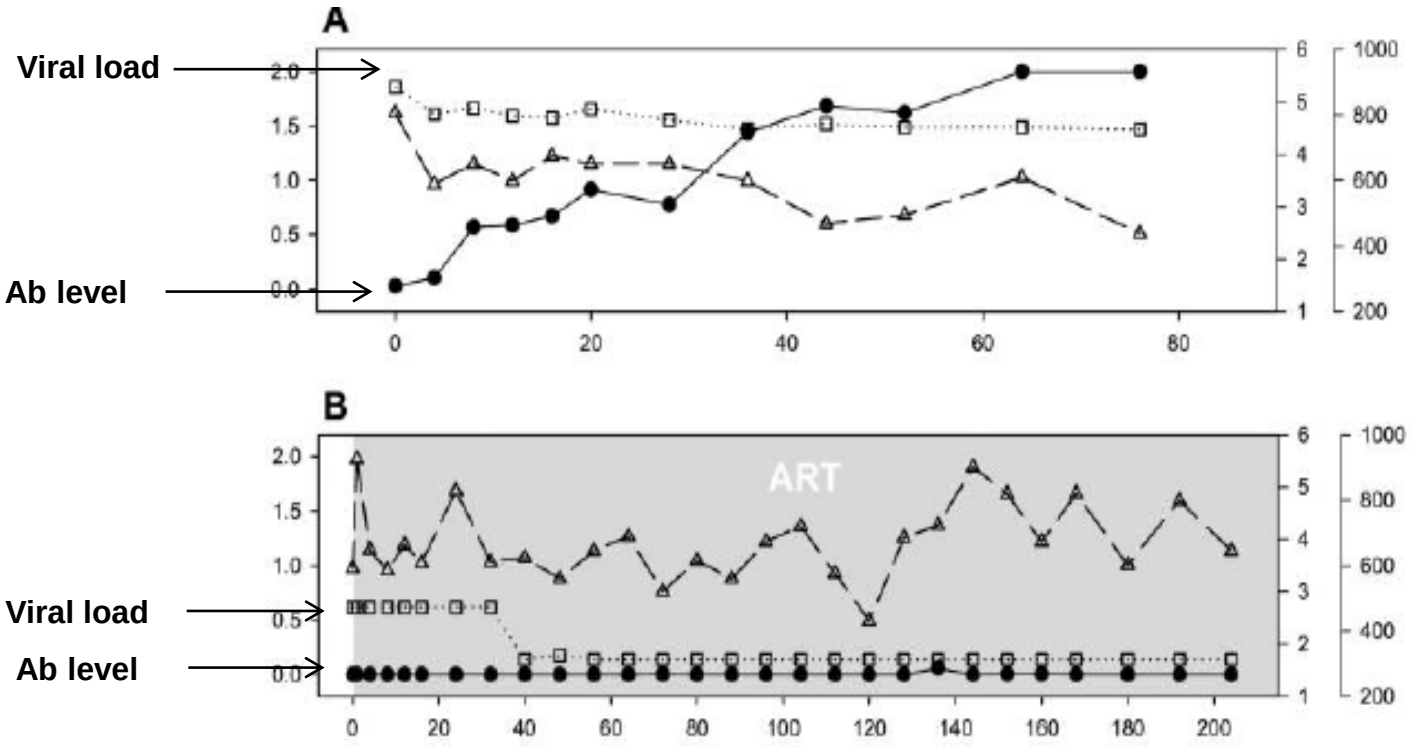


Public Health England HIV testing algorithm



Impact of PEP on anti-HIV antibody production

- Failure of screening assay antibody production



Killian et al. AIDS res Hum Retro 2006;22:640-647.

Impact of PEP on anti-HIV western blot antibody production

Patient, day after presentation[a]	ELISA result (optical density)	Western blot result, band[b]				HIV-1 load, copies/mL[c]
		p24	gp160	p40	p51/55	
Patient 1						
0	Negative	...	...	...	...	>500,000[d]
1	...	...	...	...	...	...
12	Weakly positive	<1	+1	...	...	16,300
19	...	...	...	...	...	1140
40	...	...	...	...	...	190
69	Weakly positive	...	...	...	...	<50
124	Weakly positive	<1	+1	...	...	<50
201	Weakly positive (0.139)	...	<1	...	...	<50
334	Negative	NR	NR	NR	NR	<50
432	Negative	NR	NR	NR	NR	<50
516	Negative	NR	NR	NR	NR	<50
620	Weakly positive (0.068)	NR	NR	NR	NR	<50
719	Negative	...	...	...	...	<50
866	Negative	...	...	...	...	<50
1007	Weakly positive (0.208)	NR	NR	NR	NR	<50
1174	Weakly positive (0.181)	NR	NR	NR	NR	<50
1432	Negative	...	...	...	...	<50
1700	Negative	NR	NR	NR	NR	<50

Kassutto et al. CID 2005;40:868-73.

Time course of HIV RNA and antibody levels upon ART cessation

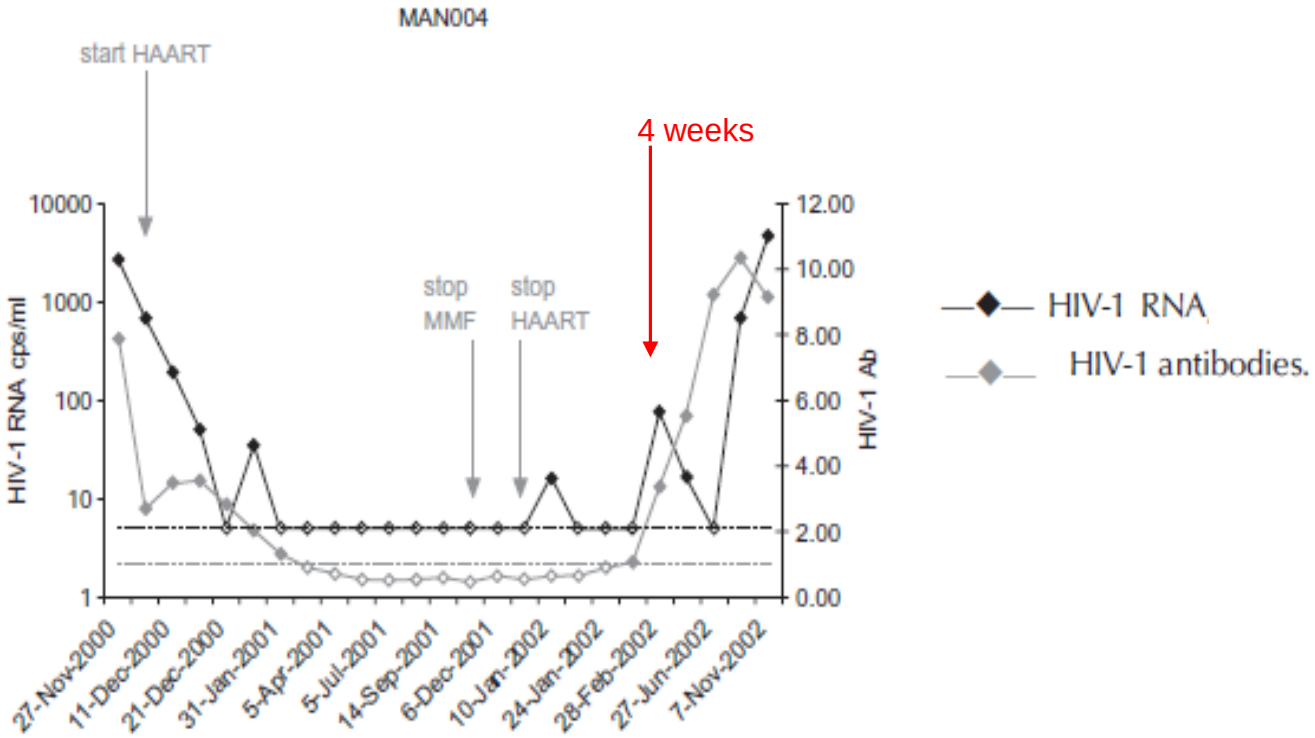
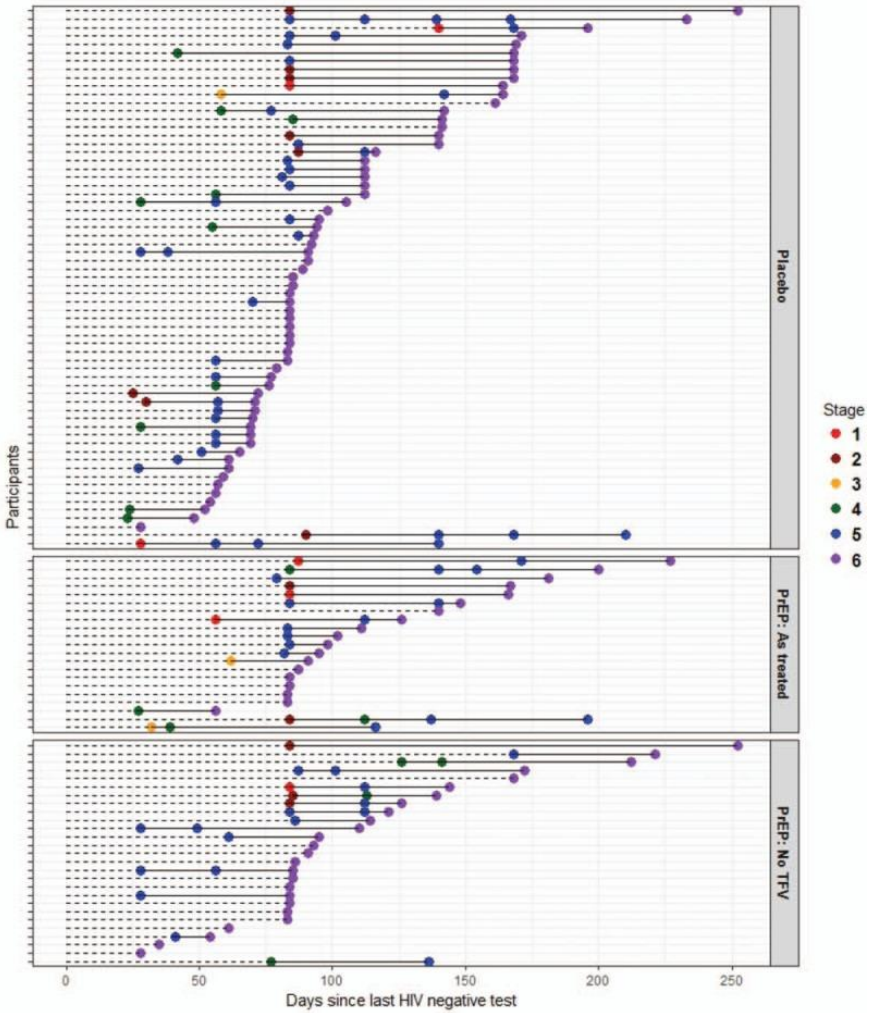


Fig. 1. Changes in plasma HIV-1 RNA and serum antibody levels over time in an HIV-1 seroreverter (subject MAN004).

Jurriaans et al. AIDS 2004;22:1607-14.

What about PrEP and diagnosis?

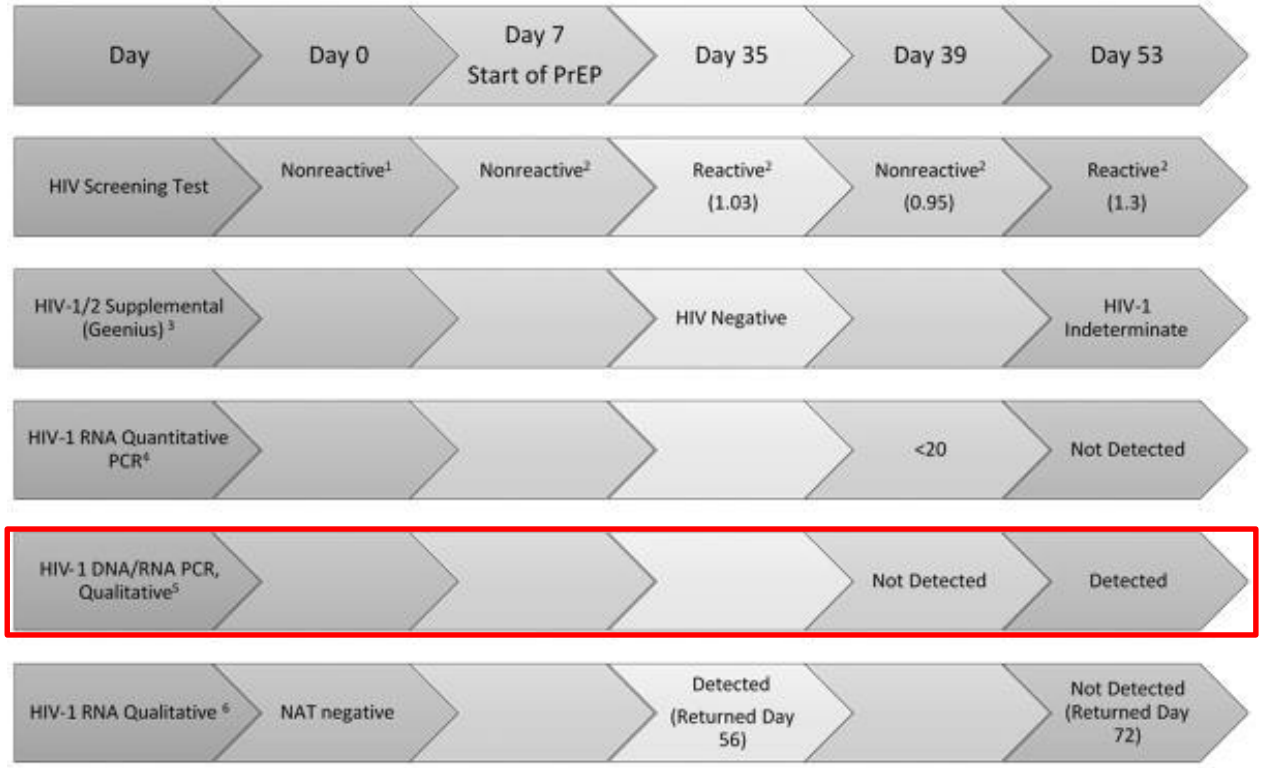
- Delayed seroconversion reported in PrEP trials
  - Thought due to lower viral loads



Donnell D, et al. AIDS. 2017;31(14):2007–2016.

May need HIV proviral DNA detection in PrEP for diagnosis

- 6 PrEP failure cases recorded out of hundreds of thousands taking PrEP
- New York case:



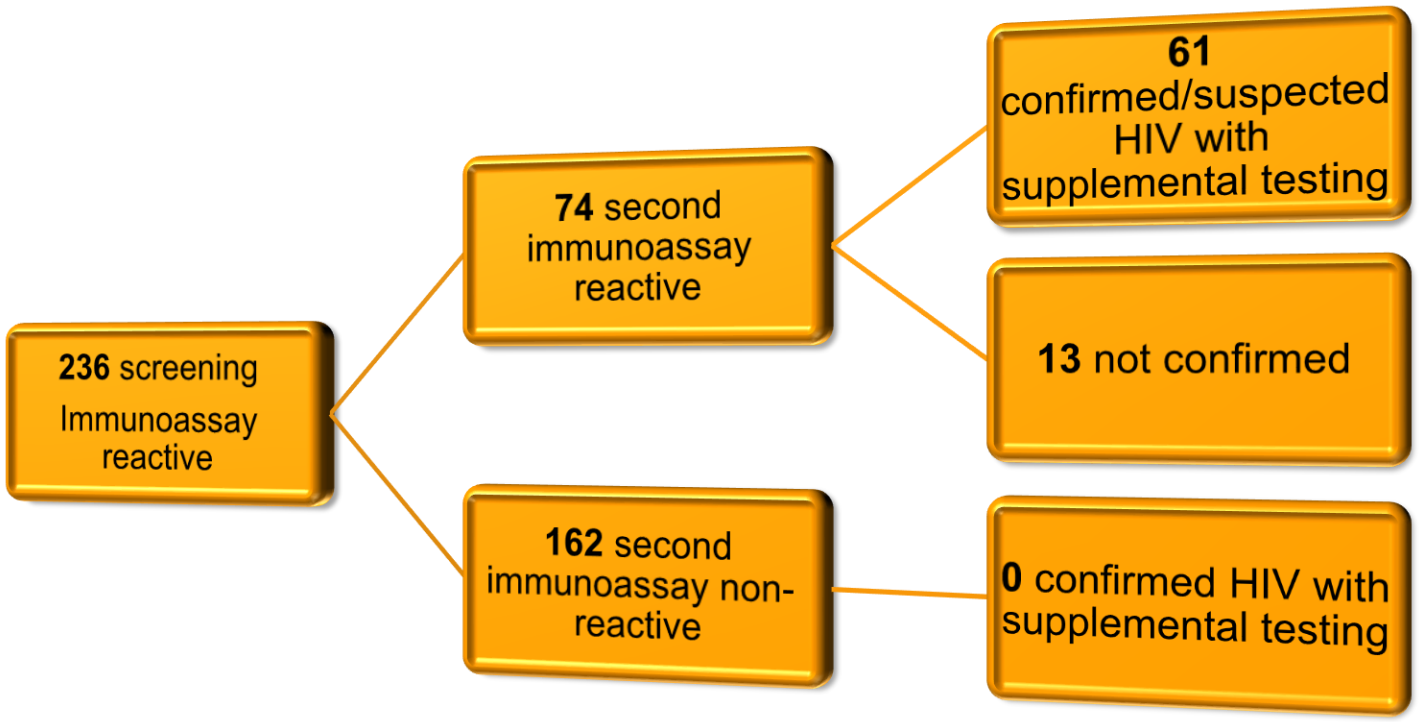
J Acquir Immune Defic Syndr. 2018 June 01; 78(2): e11–e13.

Proposed Australian laboratory diagnosis

- Add ‘Detection of HIV nucleic acid (RNA or proviral DNA)’ to *Laboratory Definitive Evidence*
  - Now class 4 (diagnostic) TGA listed commercial NAATs available for HIV-1 on plasma or serum
    - One test for HIV-1/2 (qualitative)
  - No total nucleic acid tests for whole blood ARTG listed
    - GeneXpert HIV qualitative as TGA ‘authorised prescriber’ for neonates

- Revise the 2013 NPAAC requirements for laboratory testing for HIV and HCV
  - Modify to allow diagnostic NAAT (RNA or DNA) confirmation

Can we give a faster negative result?
A two immunoassay algorithm to exclude HIV



PathWest data, 2018